

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

CADENCE COLLINS, individually and as Next
Friend of her minor child K.H.,

Plaintiff,

vs.

MEAD JOHNSON & COMPANY LLC, and
MEAD JOHNSON NUTRITION COMPANY, et al.

Defendants.

No. 4:24-cv-01005

JURY TRIAL DEMAND

**MEAD JOHNSON & COMPANY, LLC AND MEAD JOHNSON NUTRITION
COMPANY'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S
PETITION**

Defendants Mead Johnson & Company, LLC ("MJC") and Mead Johnson Nutrition Company ("MJNC") (collectively, "Mead Defendants" or "Mead Johnson"), by and through their undersigned counsel, hereby answer the Petition of K.H., a minor, by and through her Next Friend, Cadence Collins ("Plaintiff"), as follows:

The headings contained in the Complaint are reproduced here for clarity. Mead Johnson denies any allegations or characterizations in headings or the preamble of the Complaint. Any and all allegations not expressly and specifically admitted in this Answer are denied.

NATURE OF THE ACTION

1. This action arises out of the injuries suffered by K.H. when, as a premature infant, she received Mead Johnson's cow's milk-based infant feeding products while at St. Louis Children's Hospital ("Childrens"). Mead Johnson's products caused K.H. to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result, K.H. was seriously injured,

resulting in long-term health effects.

ANSWER: Mead Johnson admits that NEC is a serious, sometimes fatal condition, and that it involves necrosis of the intestinal wall. It admits that Plaintiff Collins purports to bring this action against Mead Johnson for alleged injuries to K.H. and that Plaintiff Collins, the mother of the named infant, has also brought her own claims. Mead Johnson expressly declines to adopt Plaintiffs' use of the phrase "cow's-milk-based infant formula products" and will refer to Mead Johnson products as "Enfamil Premature Nutrition Products" unless specifically stated otherwise. Except as expressly admitted, Mead Johnson denies each and every remaining allegation regarding Mead Johnson in Paragraph 1. The remaining allegations of Paragraph 1 are not directed at Mead Johnson and therefore no response is required. To the extent a response is required, Mead Johnson denies those allegations.

2. Plaintiffs bring this cause of action against Defendants to recover for injuries that are the direct and proximate result of K.H. receiving Mead Johnson's unreasonably dangerous cow's milk-based infant feeding products.

ANSWER: Mead Johnson admits that Plaintiff Collins purports to bring this action to seek recovery against Mead Johnson and Jessica Mackey. Mead Johnson denies each and every remaining allegation of Paragraph 2.

PARTIES

3. Plaintiff Cadence Collins is a natural person and a resident of Illinois. Ms. Collins is the mother of Plaintiff K.H., a minor.

ANSWER: Mead Johnson states that it lacks sufficient knowledge or information to form a belief of the truth of the allegations of Paragraph 3 and on that basis denies them.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is in Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, are manufacturers of cow's milk-based infant feeding products and market many of these products

under the "Enfamil" brand name.

ANSWER: Mead Johnson admits the allegations of the first sentence of Paragraph 4. Mead Johnson denies the allegations of the second sentence of Paragraph 4. Mead Johnson admits the third sentence of Paragraph 4. The fourth sentence of Paragraph 4 is a legal conclusion to which no response is required. To the extent a response is required, Mead Johnson admits that MJNC is the sole member of MJC. Mead Johnson further admits that MJC manufactures infant formula, including products marketed under the Enfamil brand name. Mead Johnson denies each and every remaining allegation of Paragraph 4.

5. Defendant Jessica Mackey is a sales representative for Mead Johnson. Upon information and belief, she has served in this position since August 2018. Ms. Mackey is a natural person and resident of St. Louis, MO.

ANSWER: The allegations of Paragraph 5 are not directed at Mead Johnson and therefore no response is required. To the extent a response is required, Mead Johnson admits them.

JURISDICTION AND VENUE

6. At all relevant times, Defendants had, and continue to have, regular and systematic contact with and conduct business in and from the State of Missouri, such that they have purposefully availed themselves of the laws of the State and expect to both sue and be sued in Missouri. In the alternative, Defendants' presence in the State of Missouri satisfies the due process requirements for Missouri courts to exercise jurisdiction over them. In the alternative, Defendants have consented to the exercise of jurisdiction over them by Missouri courts by registering and conducting business from the State of Missouri. In the alternative, Defendant Jessica Mackey resides in and is a citizen of the State of Missouri.

ANSWER: The allegations of Paragraph 6 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies the allegations of Paragraph 6, insofar as they relate to Mead Johnson. Mead Johnson admits that Jessica Mackey resides in the State of Missouri. It lacks knowledge or information sufficient to admit or deny the remaining allegations of Paragraph 6, and therefore denies the same.

7. Missouri's general venue statute, Mo. Rev. Stat. § 508.010.4, provides as follows:

Notwithstanding any other provision of law, in all actions in which there is any count alleging a tort and in which the plaintiff was first injured in the state of Missouri, venue shall be in the county where the plaintiff was first injured by the acts or conduct alleged in the action.

ANSWER: The allegations of Paragraph 7 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies the allegations of Paragraph 7, insofar as they relate to Mead Johnson.

8. Venue is proper in the Twenty-Second Judicial Circuit pursuant to Mo. Rev. Stat. § 508.010.4 because Plaintiff K.H. developed NEC after first being exposed to Mead Johnson's products while receiving care in St. Louis, Missouri.

ANSWER: The allegations of Paragraph 8 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies the allegations of Paragraph 8.

FACTUAL ALLEGATIONS

KH. 's NEC Diagnosis

9. K.H. was born prematurely at Barnes-Jewish Hospital in St. Louis, Missouri on September 4, 2021. She was 25 weeks and 3 days gestational age.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief of the truth of the allegations of Paragraph 9, and on that basis denies the same.

10. K.H. initially received human milk and human milk-based products. Notwithstanding that diet, K.H. was diagnosed with medical NEC on September 15, 2021. Fortunately, her medical NEC was able to be treated with antibiotics.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief of the truth of the allegations of Paragraph 10, and on that basis denies the same.

11. Following resolution of her medical NEC, K.H. was again fed a human milk diet, on which she remained healthy and was developing well.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief of the truth of the allegations of Paragraph 11, and on that basis denies the same.

12. K.H. reached 32 weeks gestational age on October 20, 2021. On or about that day, and notwithstanding her prematurity and previous diagnosis of medical NEC, she was transitioned to Enfamil formula.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief of the truth of the allegations of Paragraph 12, and on that basis denies the same.

13. Almost immediately, K.H. began to develop significant symptoms of NEC.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief of the truth of the allegations of Paragraph 13, and on that basis denies the same.

14. The disease progressed rapidly, and K.H. was required to undergo surgery on October 22, 2021. It was the first of multiple surgeries K.H. would be forced to endure as a result of NEC.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief of the truth of the allegations of Paragraph 14, and on that basis denies the same.

15. K.H.'s recurrent NEC was induced by Mead Johnson's formula. As a result of that formula feeding, K.H. suffered and continues to suffer from permanent and severe injuries.

ANSWER: Mead Johnson denies the allegations of Paragraph 15.

Cow's Milk-Based Feeding Products Are Known To Cause NEC

16. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

ANSWER: Mead Johnson admits that NEC can be a very serious condition, and can lead to morbidity and mortality. Paragraph 16 purports to summarize the development of necrotizing enterocolitis (“NEC”) and how it affects the gastrointestinal track of premature infants. Mead Johnson states that the pathology of NEC is complex, as is the structure, composition and function of a premature infants’ gastrointestinal tract. Plaintiff’s summary grossly oversimplifies complex anatomical structure and physiological processes, the

development of NEC, and its mortality risks, so as to be incomplete and inaccurate, and on that basis the allegations of Paragraph 16 are denied. Mead Johnson denies the remaining allegations of Paragraph 16.

17. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

ANSWER: Mead Johnson admits that preterm and low-birth-weight infants face risks of developing NEC, with the highest risks in the smallest and most premature infants, and the least risks in those who are closest to term and normal birth-weight. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 17.

18. For example, in one randomized, multicenter study of 926 preterm infants, NEC was *six to ten* times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and *three times* more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was *20 times more common* in those only fed cow's milk formula than in those fed breast milk.

ANSWER: Paragraph 18 purports to summarize the findings and conclusions of a specific study, which Plaintiffs have neither identified nor attached. Mead Johnson states that the report of the study speaks for itself. The study has material weaknesses and important limitations. Mead Johnson denies Plaintiff's characterization and interpretation of the study, and denies the relevance of the literature to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 18.

19. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were *90% less likely* to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

ANSWER: Paragraph 19 purports to summarize the findings and conclusions of a specific study which Plaintiff fails to identify or attach. Mead Johnson states that the report of the study speaks for itself. The study has material weaknesses and important limitations. Mead

Johnson denies Plaintiff's characterization and interpretation of the study, and denies the relevance of the study to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 19.

20. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

ANSWER: Paragraph 20 purports to summarize the findings and conclusions of a specific study which Plaintiff has not identified or attached. Mead Johnson states that the report of the study speaks for itself. The study has material weaknesses and important limitations. Mead Johnson denies Plaintiff's characterization and interpretation of the study, and denies the relevance of the study to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 20.

21. A Surgeon General report, *The Surgeon General's Call to Action to Support Breastfeeding*, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are *138% more likely* to develop NEC.

ANSWER: Mead Johnson admits that Paragraph 21 purports to quote and to summarize the findings and conclusions of a Surgeon General report cited therein. Mead Johnson states that the report speaks for itself. Plaintiff has omitted important content and context from their summary. Mead Johnson denies Plaintiff's characterization and interpretation of the report, and denies the relevance of the report to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 21.

22. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that *all* premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of ... NEC."

ANSWER: Mead Johnson admits that Paragraph 22 purports to quote and to summarize statements and recommendations of the American Academy of Pediatrics, which Plaintiff has not identified or attached. Mead Johnson states that the statements and recommendations of the AAP speak for themselves. Plaintiff has omitted important information and context from their summary. Mead Johnson denies Plaintiff's characterization of the statements and recommendations, and denies the relevance of the statements and recommendations to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 22.

23. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC ***21% of the time.***

ANSWER: Paragraph 23 purports to summarize the findings and conclusions of a specific study which Plaintiff has not identified or attached. Mead Johnson states that the report of the study speaks for itself. The study has material weaknesses and important limitations. Mead Johnson denies Plaintiff's characterization and interpretation of the study, and denies the relevance of the study to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 23.

24. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

ANSWER: Paragraph 24 purports to summarize the findings and conclusions of a specific study, which Plaintiff has not identified or attached. Mead Johnson states that the report of the study speaks for itself. The study has material weaknesses and important limitations. Mead Johnson denies Plaintiff's characterization and interpretation of the study, and denies the

relevance of the study to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 24.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

25. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

ANSWER: Mead Johnson admits that preterm and low birth-weight infants may receive nutrition consisting of mother's breast milk, donor breast milk, liquid human milk fortifiers containing human milk, human milk fortifiers that do not contain human milk, other medical foods, and/or formula. The nutritional value and availability of these alternatives varies, and the selection of appropriate nutrition for individual infants is made by expert medical personnel. Mead Johnson admits that the allegations of Paragraph 25 purport to provide broad, generalized information regarding the sources of nutrition for premature and/or low birthweight infants. Mead Johnson states that the allegations of Paragraph 25 are grossly oversimplified so as to be misleading, but admits that human donor milk may sometimes be available for use in preterm infants whose mothers do not supply their own breast milk. Mead Johnson denies the remaining allegations of Paragraph 25.

26. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the benefits of a breast milk diet.

ANSWER: Mead Johnson denies the first sentence of Paragraph 26, but admits that human milk and human milk fortifiers based on human milk can furnish adequate nutrition in

some circumstances. The benefits and risk of a particular infant feeding regimen depend on many circumstances, which Paragraph 26 fails to acknowledge. Paragraph 26 also purports to summarize a specific study which Plaintiff has not cited nor attached. The report of the study speaks for itself. The study contains material limitations and weaknesses. Mead Johnson denies Plaintiff's characterization and interpretation of the study, and denies the relevance of the study to this case. Mead Johnson denies all remaining allegations and innuendo of Paragraph 26.

27. Mead Johnson's products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk has a lower risk profile for the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

ANSWER: The allegations of Paragraph 27 also purport to summarize a study which Plaintiff has not identified or attached. The report of the study speaks for itself. The study has material weaknesses and limitations. Mead Johnson denies Plaintiff's characterization and interpretation of the study, and denies its relevance to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 27.

28. For the above reasons, specialized experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

ANSWER: Mead Johnson admits that breast milk offers many benefits to preterm and low birth-weight infants, but further states that breast milk is often unavailable and, even when available, will not always meet the preterm or low birth-weight infant's extraordinary nutritional needs. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 28.

29. At the time K.H. received Mead Johnson's products, the science clearly demonstrated to Mead Johnson that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

ANSWER: Mead Johnson denies each and every allegation of Paragraph 29.

30. Despite the scientific consensus among experts that Mead Johnson's cow's milk-based products present a dire threat to the health and development of preterm infants, Mead Johnson has made no changes to its products or the products' packaging, guidelines, instructions, or warnings. Instead, Mead Johnson has continued to sell its unreasonably dangerous products to unsuspecting parents and to healthcare providers, generating huge profits as a result.

ANSWER: Mead Johnson denies each and every allegation of Paragraph 30.

Mead Johnson's False And Misleading Marketing Regarding

Cow's Milk Based Infant Products

31. Mead Johnson has aggressively marketed its cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to K.H.'s birth.

ANSWER: Mead Johnson denies each and every allegation of Paragraph 31.

32. Mead Johnson's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that Mead Johnson's cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. *None* of Mead Johnson's marketing materials, including its promotional websites, reference the science showing how significantly its products increase the risk of NEC.

ANSWER: The allegations of Paragraph 32 are scurrilous and irrelevant. Mead Johnson denies each and every allegation of Paragraph 32.

33. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

ANSWER: Paragraph 33 purports to quote and to summarize the findings and conclusions of the studies that Plaintiffs has failed to identify or attach. Mead Johnson states that the purported studies speak for themselves. Mead Johnson denies Plaintiff's characterization and interpretation of the studies, and denies the relevance of the studies to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 33.

34. Undoubtedly aware of the impact of its advertising, Mead Johnson, along with other formula manufacturers, are willing to spend massive sums to disseminate its message, with

one study estimating that formula manufacturers collectively spent \$4.48 billion on marketing and promotion in 2014 alone.

ANSWER: The allegations of Paragraph 34 are scurrilous and irrelevant. Mead Johnson denies each and every allegation and innuendo of Paragraph 34.

35. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly-the decision-making body of the World Health Organization-developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

ANSWER: The allegations of Paragraph 35 are scurrilous and irrelevant. Paragraph 35 purports to summarize information and documents relating to the World Health Assembly ("WHA") described therein. Mead Johnson states that the documents speak for themselves. Mead Johnson denies Plaintiff's characterization of the documents, and denies the relevance of the documents to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 35.

36. While Mead Johnson acknowledges the Code on its websites and claims to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, Mead Johnson's aggressive marketing exploits new parents' darkest fears-that the nutrition they are supplying to their child will not provide the best chance of survival-while wholly failing to warn that its products come with a significantly increased risk of NEC.

ANSWER: The allegations of Paragraph 36 are scurrilous and irrelevant. Mead Johnson states that it supports the International Code of Marketing of Breast-milk Substitutes ("Code"). Mead Johnson denies each and every allegation and innuendo of Paragraph 36.

37. Mead Johnson markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead Johnson emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the deficits

and dangers that accompany its preterm products. For example, the since-edited webpage for Enfamil EnfaCare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

ANSWER: The allegations of Paragraph 37 are scurrilous and irrelevant. Mead Johnson admits that MJC sells a number of nutrition products designed to meet the nutritional needs of premature infants, including the products listed in Paragraph 34. Mead Johnson's website speaks for itself. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 37.

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive **breast milk studies** to date" (emphasis added).

ANSWER: The allegations of Paragraph 38 are scurrilous and irrelevant. Mead Johnson admits that Enfamil products are designed to meet the nutritional needs of premature infants, including but not limited to Enfamil NeuroPro EnfaCare Infant Formula ("Enfamil NeuroPro"). Mead Johnson admits that Paragraph 38 purports to quote a portion of an advertisement and a webpage for Enfamil NeuroPro, which speak for themselves. Mead Johnson's advertising is truthful, non-misleading, and constitutionally protected speech. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 38.

39. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free formula, coupons, and even entire gift baskets to parents in hospitals, medical clinics, and residential charities where out-of-town families stay while their babies receive long-term treatment in the NICU.

ANSWER: The allegations of Paragraph 39 are scurrilous and irrelevant. Mead Johnson denies each and every allegation and innuendo of Paragraph 39.

40. Ms. Mackey was responsible for convincing hospital personnel, including personnel at the hospitals where K.H. was treated and developed NEC, to give Mead Johnson's products to infants and/or to convince parents like Cadence Collins to allow their children to be fed those products.

ANSWER: The allegations of Paragraph 40 are not directed at Mead Johnson and therefore no response is required. To the extent a response is required, Mead Johnson denies them.

41. In connection with her job duties, Ms. Mackey provided information about Mead Johnson's products to hospital personnel, including personnel at the hospitals where K.H. was treated and developed NEC. Mead Johnson sales representatives, including Ms. Mackey, routinely misrepresented the risks and benefits of Mead Johnson's products versus human milk and human milk products, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

ANSWER: The allegations of Paragraph 41 are scurrilous and irrelevant. Mead Johnson denies each and every allegation and innuendo of Paragraph 41.

42. Through Mead Johnson's early targeting, it creates brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use its term and toddler formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for Mead Johnson. Mead Johnson's gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their health care professionals, and they have been shown to negatively impact breastfeeding rates.

ANSWER: The allegations of Paragraph 42 are scurrilous and irrelevant. Mead Johnson denies each and every allegation and innuendo of Paragraph 42.

43. Further, upon recognition of a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Mead Johnson developed "Enfamil Human Milk Fortifier." This name is misleading in that it suggests that the product is derived from breast milk, when, in fact, it is a cow's milk-based product. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:



ANSWER: The allegations of Paragraph 43 are scurrilous and irrelevant. Mead Johnson admits that the images of Enfamil Human Milk Fortifier packaging contained in Paragraph 43 are marketing assets that have been employed with Enfamil Human Milk Fortifier. It admits that Enfamil Premature Nutrition Products, including Enfamil Human Milk Fortifier, are designed to meet the nutritional needs of premature infants. Paragraph 43 purports to quote and to summarize an unspecified study that Plaintiff has not identified or attached. Mead Johnson states that the report of the study speaks for itself. It denies Plaintiff's characterization and interpretation of the study, and denies the relevance of the study to this case. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 43.

44. parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider Mead Johnson's cow's milk-based products to be a first choice. This marketing scheme is employed despite Mead Johnson knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like K.H.

ANSWER: The allegations of Paragraph 44 are scurrilous and irrelevant. Mead Johnson denies each and every allegation of Paragraph 44.

Mead Johnson's Inadequate Warnings

45. Mead Johnson promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

ANSWER: Mead Johnson denies each and every allegation of Paragraph 45.

46. The Enfamil products Mead Johnson markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

ANSWER: Mead Johnson admits that one product, Enfamil EnfaCare®, can be purchased at retail locations. It also admits that products intended for premature infants can be legally sold without a prescription. However, with the exception of EnfaCare, Mead Johnson does not make premature products generally available for sale at retail locations. There is no consumer market for Enfamil Human Milk Fortifier or Enfamil Premature (in its various calorie counts), and Mead Johnson does not market these products to consumers. Use of these products in NICU settings is mediated by learned intermediaries, and post-discharge, caregivers are instructed to consult with a physician about formula usage. Mead Johnson denies each and every remaining allegation of Paragraph 46.

47. Despite knowing of the risk of NEC, the packaging of Mead Johnson's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead Johnson's products, or of the magnitude of this increased risk. Mead Johnson likewise did not provide instructions or guidance for how to avoid NEC.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 47.

48. Mead Johnson cites no medical literature or research to guide the use of its products.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 48.

49. Despite knowing of the risk of NEC, Mead Johnson did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead Johnson likewise did not provide instructions or guidance for how to avoid NEC.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 49.

50. Mead Johnson deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 50.

51. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead Johnson failed to require or recommend that medical professionals or hospitals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 51.

Safer Alternative Designs

52. Mead Johnson's cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. Mead Johnson could have used pasteurized breast milk instead of cow's milk in its products, which would have produced a safer product.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 52.

53. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

ANSWER: Mead Johnson admits that Prolacta Bioscience sells infant nutrition products containing breast milk. Mead Johnson denies each and every remaining allegation of Paragraph 53.

54. On information and belief, Mead Johnson was aware of the significantly increased risk of NEC and death associated with its cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Mead Johnson has continued to use cow's milk as the foundation of its products.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 54.

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT

(Against Mead Johnson)

55. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER: For its response to Paragraph 55, Mead Johnson incorporates by reference its response to Paragraphs 1 through 54 as though fully set forth herein.

56. Mead Johnson, as a manufacturers and/or seller of the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute its products in a manner that was not unreasonably dangerous.

ANSWER: Mead Johnson admits that MJC manufactures and sells Enfamil Premature Nutrition Products. Mead Johnson states that the remaining allegations and innuendo of Paragraph 56 are a legal conclusion to which no response is required. To the extent a response is required, Mead Johnson complied with any duties imposed by law, and denies each and every remaining allegation and innuendo of Paragraph 56.

57. Mead Johnson also owed a duty to the consuming public in general, and Plaintiffs in particular, to manufacture, sell, and distribute its products in a manner that was merchantable and reasonably suited for their intended use.

ANSWER: Mead Johnson states that the allegations and innuendo of Paragraph 57 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it complied with any and all duties imposed by law, states that Enfamil products were merchantable and reasonably fit for their intended use, and denies each and every remaining allegation and innuendo of Paragraph 57.

58. Mead Johnson knew that its products would be used to feed premature infants like K.H. and knew (or reasonably should have known) that use of its cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, it continued to sell and market its defective products as appropriate for premature infants.

ANSWER: Mead Johnson admits Enfamil Premature Nutrition Products are intended

to feed premature infants, and are used for that purpose. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 53.

59. K.H. ingested Mead Johnson's unreasonably dangerous cow's milk-based formula. The risks of feeding that formula to K.H. outweighed the benefits. An ordinary consumer would not expect Mead Johnson's products to carry a significant risk of serious injury and death from NEC.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief of the truth as to the allegations that K.H. "ingested" Enfamil products "and on that basis denies such allegations. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 59.

60. Mead Johnson knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that Mead Johnson's products do.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 60.

61. Mead Johnson's products contained cow's milk at the time they left the manufacturing facility.

ANSWER: Mead Johnson admits that its Enfamil products contained cow's milk at the time they left the manufacturing facility. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 61.

62. Mead Johnson did not develop a human-milk based product that was safer for premature infants and did not reformulate its products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

ANSWER: Mead Johnson admits that it does not sell human milk containing products. It denies each and every remaining allegation of Paragraph 62.

63. Mead Johnson's products were fed to K.H., which directly and proximately caused her NEC and led to injury and death.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief

of the truth as to the allegations that K.H. was fed Mead Johnson products. The remaining allegations of Paragraph 63 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson denies each and every allegation and innuendo of Paragraph 63.

RESPONSE TO PRAYER FOR RELIEF: Mead Johnson denies that Plaintiffs are entitled to the relief requests, or any other relief, and requests that judgment be entered in its favor and against Plaintiffs, as set forth below.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN

(Against Mead Johnson)

64. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER: For its response to Paragraph 64, Mead Johnson incorporates by reference its response to Paragraphs 1 through 63 as though fully set forth herein.

65. Mead Johnson, as the manufacturer and/or seller of the infant products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of its products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

ANSWER: Mead Johnson admits that MJC manufactures and sells Enfamil Premature Nutrition Products. Mead Johnson states that the remaining allegations of Paragraph 61 state legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it complied with any and all duties imposed by law, and denies each and every remaining allegation and innuendo of Paragraph 65.

66. Mead Johnson's duty to warn is part of its general duty to design, manufacture, and sell its infant products in a manner that is reasonably safe for their foreseeable uses. By designing its products with cow's milk-based ingredients, Mead Johnson undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

ANSWER: Mead Johnson states that the allegations and innuendo of Paragraph 66 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it complied with any and all duties imposed by law, and denies each and every remaining allegation and innuendo of Paragraph 66.

67. Specifically, Mead Johnson breached its duty to warn of the foreseeable risks of the infant products at issue in this litigation because it knew or should have known that its cow's milk- based premature infant products would be fed to premature infants like K.H., and that its products might cause those infants to develop NEC, severe injury, or death, yet it failed to provide adequate warnings of those risks. Among other risks, Mead Johnson:

- a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like K.H.; and/or
- c. Inserted warnings and instructions on its products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failed to insert a large and prominent "black box"-type warning that its cow's milk- based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Mead Johnson's products, notwithstanding their substantial risks; and/or
- g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns; and/or
- h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 67, including all subparts.

68. Mead Johnson's products contained cow's milk at the time they left the

manufacturing facility.

ANSWER: Mead Johnson admits that its Enfamil products contained ingredients derived from cow's milk at the time they left the manufacturing facility. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 68.

69. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Mead Johnson's products, K.H. was fed cow's milk-based products, which caused her to develop NEC.

ANSWER: The allegations of Paragraph 69 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson lacks sufficient knowledge or information to form a belief of the truth as to the allegations that K.H. was fed Mead Johnson products. Mead Johnson denies each and every remaining allegation and innuendo of Paragraph 69.

70. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had Mead Johnson warned of the extreme risk associated with feeding premature infants cow's milk-based formula, physicians and health care providers would not have fed the Injured Infant those products. Had Ms. Collins known of the significant risks of feeding K.H. cow's milk-based formula, she would not have allowed such products to be fed to her child.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 70.

RESPONSE TO PRAYER FOR RELIEF: Mead Johnson denies that Plaintiffs are entitled to the relief requests, or any other relief, and requests that judgment be entered in its favor and against Plaintiffs, as set forth below.

COUNT III: NEGLIGENCE

(Against Mead Johnson and Jessica Mackey)

71. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER: For its response to Paragraph 71, Mead Johnson incorporates by reference

its response to Paragraphs 1 through 70 as though fully set forth herein.

72. Mead Johnson as the manufacturer and/or seller of the products at issue in this litigation, and Ms. Mackey, as the sales representative promoting and educating hospitals and health care providers, including K.H.'s hospital and health care providers, owed a duty to the consuming public in general, and Plaintiff in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose, and warn the consuming public of any risks associated with Mead Johnson's products.

ANSWER: Mead Johnson admits that MJC manufactures and sells Enfamil Premature Nutrition Products. Mead Johnson states that the remaining allegations in Paragraph 72 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it and Jessica Mackey complied with all duties imposed by law, and denies each and every remaining allegation and innuendo in Paragraph 72.

73. At all times relevant to this action, K.H.'s health care providers used the products at issue in their intended manner and for their intended purpose.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 73, and on that basis denies them.

74. Mead Johnson, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached its duty to the general public and Plaintiffs. Ms. Mackey, directly or indirectly, negligently marketed, sold, and/or distributed Mead Johnson's cow's milk-based infant products at issue in this litigation, including to Ms. Collins and K.H.'s caregivers, and thereby breached her duty to the general public and the Plaintiffs.

ANSWER: Mead Johnson admits that MJC manufactures, distributes, and sells Enfamil Premature Nutrition Products. Mead Johnson states that the remaining allegations in Paragraph 74 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it and Jessica Mackey complied with all duties imposed by law, and denies each and every remaining allegation and innuendo in Paragraph 74.

75. Although Mead Johnson knew or reasonably should have known at the time of production that its cow's milk-based infant products significantly increased the risk of NEC,

serious injury, and death, it failed to act in a reasonably prudent manner and breached its duty by:

- a. of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like K.H.; and/or
- c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or
- d. Failing to insert a large and prominent "black box"-type warning that its cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or
- e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or
- f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed Mead Johnson's products, notwithstanding their substantial risks; and/or
- g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 75, including all subparts.

76. Ms. Mackey knew or reasonably should have known at the time of marketing, sale, and/or distribution of Mead Johnson's cow's milk-based infant products that they significantly increased the risk of NEC, serious injury, and death; she failed to act in a reasonably prudent manner and breached her duty by:

- a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or
- b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like K.H.; and/or
- c. Failing to provide the hospitals for which she was Mead Johnson's sales representative, including K.H.'s treating hospitals, with the well-researched

and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

- d. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or
- e. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or
- f. Misrepresenting that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

ANSWER: The allegations of Paragraph 76 are not directed at Mead Johnson. Mead Johnson denies the allegations of Paragraph 76 as to Jessica Mackey, including all subparts.

77. In addition, although Mead Johnson knew or reasonably should have known at the time of production that its cow's milk-based products significantly increased the risk of NEC, serious injury, and death, it failed to act in a reasonably prudent manner and breached its duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest its products.

ANSWER: The allegations in Paragraph 77 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it complied with all duties imposed by law, and denies each and every remaining allegation and innuendo in Paragraph 77.

78. As a direct and proximate result of Mead Johnson's and Ms. Mackey's failure to act in a reasonably prudent manner and their breach of duty, K.H. was fed cow's milk-based products, which caused her to develop NEC.

ANSWER: The allegations of Paragraph 78 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies each and every allegation and innuendo of Paragraph 78, and denies all allegations as to Jessica Mackey.

79. Had Mead Johnson and Ms. Mackey satisfied their duties to the consuming public in general, K.H. would not have been exposed to their unreasonably dangerous cow's milk-based products.

ANSWER: Mead Johnson denies each and every allegation and innuendo of

Paragraph 79.

RESPONSE TO PRAYER FOR RELIEF: Mead Johnson denies that Plaintiffs are entitled to the relief requests, or any other relief, and requests that judgment be entered in its favor and against Plaintiffs, as set forth below.

COUNT IV: INTENTIONAL MISREPRESENTATION

(Against the Mead Johnson and Jessica Mackey)

80. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER: For its response to Paragraph 80, Mead Johnson incorporates by reference its response to Paragraphs 1 through 79 as though fully set forth herein.

81. At all times relevant to this action, K.H. (and Ms. Collins) used the products at issue in their intended manner and for their intended purpose.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 81, and on that basis denies them.

82. Mead Johnson as the manufacturer and/or seller of the products at issue in this litigation, and Ms. Mackey, as the sales representative promoting and educating hospitals and health care providers, including K.H.'s hospital and health care providers, about the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using Mead Johnson's products when used in the intended manner and for the intended purpose.

ANSWER: Mead Johnson admits that MJC manufactures and sells Enfamil Premature Nutrition Products. Mead Johnson states that the remaining allegations in Paragraph 82 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it and Jessica Mackey complied with all duties imposed by law, and denies each and every remaining allegation and innuendo in Paragraph 82.

83. Mead Johnson and Ms. Mackey breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

ANSWER: The allegations of Paragraph 83 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies each and every allegation and innuendo of Paragraph 83, including the allegations as to Jessica Mackey.

84. Specifically, upon information and belief, Mead Johnson and Ms. Mackey made the following false statements of material fact on an ongoing and repeated basis and prior to the time K.H. was fed their products:

- a. That Mead Johnson's cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that Mead Johnson's products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That Mead Johnson's cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that Mead Johnson's products were not necessary to achieve adequate growth; and/or
- c. That Mead Johnson's products have no serious side effects, when they knew or should have known the contrary to be true; and/or
- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That Mead Johnson's products were safe and more like breast milk than other infant products and that they had removed the hannful ingredients of cow's milk when, in fact, the cow's milk in Mead Johnson's products was still capable of causing NEC, serious injury, and death; and/or
- h. That Mead Johnson's products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that Mead Johnson's products significantly increased the risk of NEC in premature infants.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 84, including all subparts, and including all allegations as to Jessica Mackey.

85. Mead Johnson and Ms. Mackey knew or reasonably should have known those misrepresentations to be false.

ANSWER: Mead Johnson denies each and every allegation and innuendo of

Paragraph 85, including all allegations as to Jessica Mackey.

86. Mead Johnson's and Ms. Mackey's misrepresentations were intended to, and in fact did, induce hospitals and health care providers, including K.H.'s hospital and health care providers, to provide their infant products to babies, including K.H.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 86, including all allegations as to Jessica Mackey.

87. Ms. Collins was not aware that these misrepresentations were false and justifiably relied on them. Mead Johnson's and Ms. Mackey's misrepresentations induced Ms. Collins and her health care providers to allow her child to be fed Mead Johnson's infant products, in reliance on all the messaging Ms. Collins received about formula feeding, including, directly or indirectly, Mead Johnson's and Ms. Mackey's messaging. Had Mead Johnson and Ms. Mackey not committed these intentional misrepresentations, K.H. would not have been exposed to the Mead Johnson's unreasonably dangerous cow's milk-based products.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 87, including all allegations as to Jessica Mackey.

88. As a direct and proximate result, Mead Johnson's products were fed to K.H., causing her NEC and subsequent injuries.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 88.

RESPONSE TO PRAYER FOR RELIEF: Mead Johnson denies that Plaintiffs are entitled to the relief requests, or any other relief, and requests that judgment be entered in its favor and against Plaintiffs, as set forth below.

COUNT V: NEGLIGENT MISREPRESENTATION

(Against the Mead Johnson and Jessica Mackey)

89. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER: For its response to Paragraph 89, Mead Johnson incorporates by reference its response to Paragraphs 1 through 88 as though fully set forth herein.

90. At all times relevant to this action, K.H. used the products at issue in their

intended manner and for their intended purpose.

ANSWER: Mead Johnson lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 90, and on that basis denies them.

91. Mead Johnson as the manufacturer and/or seller of the products at issue in this litigation, and Ms. Mackey, as the sales representative promoting and educating hospitals and health care providers, including K.H.'s hospital and health care providers, about the products at issue in this litigation, owed a duty to the consuming public in general, and Plaintiffs in particular, to provide truthful, accurate, and complete information about the risks and benefits of using Mead Johnson's products when used in the intended manner and for the intended purpose.

ANSWER: Mead Johnson admits that MJC manufactures and sells Enfamil Premature Nutrition Products. Mead Johnson states that the remaining allegations in Paragraph 91 are legal conclusions to which no response is required. To the extent a response is required, Mead Johnson states that it and Jessica Mackey complied with all duties imposed by law, and denies each and every remaining allegation and innuendo in Paragraph 91.

92. In the course of their business, Mead Johnson and Ms. Mackey breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

ANSWER: The allegations of Paragraph 92 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies each and every allegation and innuendo of Paragraph 92, including all allegations as to Jessica Mackey.

93. Specifically, upon information and belief, Mead Johnson made the following false statements of material fact on an ongoing and repeated basis and prior to the time K.H. was fed its products:

- a. That its cow's milk-based products were safe and beneficial for premature infants when it knew or should have known that its products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or
- b. That its cow's milk-based products were necessary to the growth and nutrition of premature infants, when it knew or should have known that its products were not necessary to achieve adequate growth; and/or
- c. known the contrary to be true; and/or

- d. That cow's milk-based products were safe for premature infants; and/or
- e. That cow's milk-based products were necessary for optimum growth; and/or
- f. That cow's milk-based products were similar or equivalent to breast milk; and/or
- g. That its products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in its products was still capable of causing NEC, serious injury, and death; and/or
- h. That its products were based on up-to-date science, which made them safe for premature infants; and/or
- i. Omitting the material fact that its products significantly increased the risk of NEC in premature infants.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 93, including all subparts, and including all allegations as to Jessica Mackey.

94. Upon information and belief, Ms. Mackey made the same false statements of material fact on an ongoing and repeated basis including to individuals at K.H.'s treating hospitals and prior to the time K.H. was fed Mead Johnson's products. Upon information and belief, Ms. Mackey also represented that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

ANSWER: Mead Johnson denies each and every of the allegations of Paragraph 94.

95. Mead Johnson and Ms. Mackey were negligent or careless in not determining those representations to be false.

ANSWER: The allegations of Paragraph 95 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies each and every allegation and innuendo of Paragraph 95, including all allegations as to Jessica Mackey.

96. Mead Johnson's and Ms. Mackey's misrepresentations were intended to and did in fact induce hospitals and health care providers, including K.H.'s health care providers, to provide Mead Johnson's products to babies, including K.H.

ANSWER: The allegations of Paragraph 96 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies each and every

allegation and innuendo of Paragraph 96, including all allegations as to Jessica Mackey.

97. Mead Johnson's and Ms. Mackey's misrepresentations induced, and were intended to induce, Ms. Collins to allow her child to be fed Mead Johnson's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, Mead Johnson's and Ms. Mackey's messaging. Had Mead Johnson and Ms. Mackey not committed these negligent misrepresentations, K.H. would not have been exposed to Mead Johnson's unreasonably dangerous cow's milk-based products.

ANSWER: The allegations of Paragraph 97 state a legal conclusion, to which no response is required. To the extent a response is required, Mead Johnson denies each and every allegation and innuendo of Paragraph 97, including all allegations as to Jessica Mackey.

98. As a direct and proximate result, Mead Johnson's products were fed to K.H., causing her NEC and subsequent injuries.

ANSWER: Mead Johnson denies each and every allegation and innuendo of Paragraph 98.

RESPONSE TO PRAYER FOR RELIEF: Mead Johnson denies that Plaintiffs are entitled to the relief requests, or any other relief, and requests that judgment be entered in its favor and against Plaintiffs, as set forth below.

AFFIRMATIVE DEFENSES

In further response to the Complaint, Mead Johnson pleads the following affirmative defenses to the claims of Plaintiff Cadence Collins, on her own behalf and on behalf of her minor child K.H. By raising these defenses, Mead Johnson does not concede that it has the burden of proof as to any such defense. Mead Johnson reserves the right to supplement or amend its defenses as may be proper based on the pleadings filed, the outcome of its pending motion to dismiss, and discovery taken in this action.

FIRST AFFIRMATIVE DEFENSE

Mead Johnson alleges that the Enfamil products fed to K.H. were selected and administered by doctors and other medical professionals, including registered dietitians, in

accordance with their clinical judgment as to what feeding regimens would give K.H. the best possible outcome. These learned intermediaries are knowledgeable about the scientific rationale for the Enfamil products, and about the open medical literature relating to various feeding alternatives. These intermediaries provide advice to parents and caregivers in accordance with their best judgment, including relevant warnings relating to product risks. Under such circumstance, the duty to inform, warn, and educate about the Enfamil products ran to the learned intermediaries, not directly to the parents and infant caregivers. Mead Johnson provided sufficient information about the Enfamil products, including the cow's milk ingredient, to permit these learned intermediaries to make informed determinations as to the use of the products, and to decide what warnings to convey to parents and caregivers.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's entitlement to damages, if any, is barred, in whole or part, by virtue of the doctrine of *res judicata*, and/or by virtue of release, and/or by virtue of payment by the health care providers who cared for K.H. For any harm, there can be but one recovery. *Scruggs v. Greyhound Lines, Inc.*, No. 4:12CV2080 JCH, 2013 WL 2630334, at *3 (E.D. Mo. June 11, 2013) (citing *Kforce, Inc. v. Surrex Solutions Corp.*, 436 F.3d 981, 984 (8th Cir.2006)) ("It is well settled in Missouri that a party cannot be compensated for the same injury twice"). On information and belief, Plaintiff has already recovered for the alleged harm, and any recovery in this case would allow double recovery.

THIRD AFFIRMATIVE DEFENSE

Mead Johnson states that if Plaintiff sustained any injuries or damages, which fact is specifically denied, and it is determined that said injuries or damages were caused, in whole or in part, by the act, omission, negligence, or fault of other persons or entities for whom Mead

Johnson is not responsible, and such act, omission, negligence, or fault does not act as a complete bar to Plaintiff's claims against Mead Johnson, then Mead Johnson is entitled to an apportionment of all such causal fault and a reduction of any award against it. *See, e.g.*, Mo. Rev. Stat. § 537.060.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff had notice of the facts and circumstances alleged in the Complaint for an unreasonable amount of time prior to the filing this action, including as early as the infant's diagnosis of and treatment for NEC in 2017. Mead Johnson denies Plaintiff's allegations as set forth above, but, pleading in the alternative, states that Plaintiff nevertheless refrained from commencing an action against the Mead Johnson, and such delay caused prejudice to Mead Johnson. Therefore, Plaintiff is barred from relief under the equitable doctrines of laches, waiver and/or estoppel.

FIFTH AFFIRMATIVE DEFENSE

Mead Johnson alleges that the sole proximate cause of the injuries and damages alleged in the Petition was the actions, non-actions, or negligence of persons other than Mead Johnson, and for whose actions, non-actions, or negligence, Mead Johnson is in no way liable. Plaintiff, therefore, is not entitled to recover from Mead Johnson because of this lack of proximate causation.

SIXTH AFFIRMATIVE DEFENSE

Mead Johnson alleges that each of the Enfamil products intended for premature infants supports growth and development in such infants. Each of these products has features that allow physicians and hospital dieticians to provide precise calorie counts, and other nutritional components, that enable premature infants to grow and develop commensurately with what

premature infants would experience *in utero*. Certain Enfamil products can be used to enhance the nutritional profile of breast milk, including donor breast milk, which by itself does not provide sufficient calories, protein, and certain nutrients to meet growth and development objectives. Liquid human milk fortifiers, such as those manufactured by Prolacta, displace volume of donor and mother's breast milk, and clinicians may have other good reasons not to use it. The Enfamil products can also be used when breast milk is not available, is too expensive, or is otherwise not warranted in the judgment of the physicians and hospital dieticians. The Enfamil products thus have many benefits and great utility in managing the growth and development of premature/low birth-weight infants in NICU settings. These benefits outweigh any alleged risks, which risks are denied.

SEVENTH AFFIRMATIVE DEFENSE

The Enfamil product of which Plaintiff complains contains cow's milk, which has certain unavoidable, inherent characteristics that cannot be altered or obviated under the state of scientific knowledge existing at the time such product(s) were manufactured. While denying that cow's milk, or its derivative are dangerous or defective, if Plaintiff's child sustained any injuries as a result of using or exposure to the product(s) at issue, those injuries were the result of properties necessarily associated with the products that were unavoidable and for which Mead Johnson cannot be held responsible.

EIGHTH AFFIRMATIVE DEFENSE

Mead Johnson alleges that Plaintiff's claims are expressly and impliedly preempted, in whole or in part, by federal statutes and regulations. The Enfamil products at issue in this case were either exempt formulas, or medical foods, or routine formulas, and all were regulated by the United States Food and Drug Administration ("FDA"). In fact, infant formulas are the most

regulated food products sold in the United States, and comprehensive federal regulations control the content, labeling, and instructions relating to the products. The conduct of Mead Johnson in all activities with respect to the subject products has been and is under the supervision of the FDA, which has supreme regulatory authority to ensure that products fed to infants are safe, and not adulterated or misbranded. At no time has FDA disapproved any of the Enfamil products at issue in this case, nor has it endorsed any of the scientific and medical opinions set forth in Plaintiff's Petition. Plaintiff's claims would thwart and undermine the implementation of important federal policies, including those relating to the availability of safe alternatives to human breast milk. Moreover, to the extent that Plaintiff's claims are based on alleged misrepresentations made to the FDA, or upon non-compliance with, or violations of, the Food Drug and Cosmetic Act ("FDCA"), Plaintiff's claims are preempted, and Plaintiff lacks standing to enforce any alleged violations. *Buckman Co. v. Plaintiff's Legal Comm*, 531 U.S. 341 (2001).

NINTH AFFIRMATIVE DEFENSE

Mead Johnson realleges and incorporates the allegations of the Eighth Affirmative Defense as if fully set forth herein. Mead Johnson's compliance with applicable regulations is legally sufficient evidence that it complied with all legal duties under the laws of Missouri as applicable to this action. This compliance proves that the products were not unreasonably dangerous, inadequately labeled, negligently designed or manufactured, and were fully merchantable and suitable for their intended use. The compliance is also legally sufficient evidence that Mead Johnson and/or Mead Johnson did not mislead physicians or anyone else with respect to these products, and proves lack of "scienter."

TENTH AFFIRMATIVE DEFENSE

Mead Johnson states that Plaintiff's claims are barred, in whole or in part, by the doctrine(s) contained in the Restatement (Second) of Torts § 402A, Comments *j* and *k*; any similarly applicable doctrine contained in the Restatement (Third) of Torts: Products Liability; and any and all defenses set forth in state Product Liability Acts, as are applicable in the home state of the Plaintiff.

ELEVENTH AFFIRMATIVE DEFENSE

Mead Johnson alleges that all or part of the injuries, damages, and/or losses sustained by Plaintiff and/or her child (which injuries, damages and losses are denied) was a direct, proximate, and sole result of the child's physical and bodily condition on, prior to, and subsequent to events alleged in the Petition, and Plaintiff is thus barred from any recovery in this action under the doctrine of no liability for any idiosyncratic reaction.

TWELFTH AFFIRMATIVE DEFENSE

Adequate and complete warnings and instructions were provided with the subject product(s) and the subject product(s) were neither defective nor unreasonably dangerous when used according to label instruction. Accordingly, to the extent that Mead Johnson had any duty with respect to the manufacture and/or sale of its product(s), Mead Johnson fully discharged such duty by giving adequate instructions and warnings concerning the product's use. Mead Johnson invokes all state-of-the-art defenses applicable to Plaintiff's claims.

THIRTEENTH AFFIRMATIVE DEFENSE

Mead Johnson alleges that Plaintiff's child's alleged injuries or damages, if any, were solely caused by pre-existing or subsequent conditions unrelated to the product(s) at issue in this case.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's alleged damages, if they were caused by the subject product(s) (which Mead Johnson expressly denies) were caused by use of the product(s) in contravention of the warnings provided with it.

FIFTEENTH AFFIRMATIVE DEFENSE

All or part of the damages, injuries, and/or losses alleged by Plaintiff were caused by and attributable to the unintended, unreasonable, and improper use, misuse, alteration, or modification of the product(s).

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because the alleged injuries, if any, were the result of conduct by independent third parties over which Mead Johnson had no control, or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries.

SEVENTEENTH AFFIRMATIVE DEFENSE

Mead Johnson will rely upon any and all other further defenses which become available or appear during discovery proceedings in this action and hereby specifically reserve the right to amend its answer for the purpose of asserting any such additional defenses.

EIGHTEENTH AFFIRMATIVE DEFENSE

On information and belief, Plaintiff's claims are barred, in whole or in part, by the doctrines of informed consent, release, and waiver.

NINETEENTH AFFIRMATIVE DEFENSE

On information and belief, Plaintiff knowingly and voluntarily assumed any and all risks associated with the matters alleged in the Complaint. Pursuant to the doctrines of assumption of

the risk or informed consent, this conduct bars, in whole or in part, the damages and other relief that Plaintiff seeks to recover herein.

TWENTIETH AFFIRMATIVE DEFENSE

Defendant states Plaintiffs' claims should be barred or otherwise comparatively reduced by Plaintiffs' failure to mitigate damages.

TWENTY FIRST AFFIRMATIVE DEFENSE

If Defendant is found liable to Plaintiff, Defendant requests a set-off pursuant to §537.060 RSMo. for the amount of any settlement between Plaintiff and any other defendant, person, or entity, whether made a party to the action or not, who may have previously entered into a release, a covenant not to sue, or similar agreement with Plaintiff for a claim arising out of the alleged transaction which forms the basis of Plaintiffs' cause of action (hereinafter "settling tortfeasor(s)"), or the amount paid to the Plaintiff by any other defendant(s) or settling tortfeasor(s), whichever is greater.

TWENTY SECOND AFFIRMATIVE DEFENSE

Defendant intends to rely upon the provisions of §490.715, including but not limited to the provision on medical bills as set forth in §490.715.5(2) RSMo.

TWENTY THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because Mead Johnson's speech was not false or misleading, and is protected under the First Amendment of the United States Constitution and comparable provisions of applicable Missouri law. The products offer many benefits, and the types of warnings alleged by Plaintiff to be required, would be false, misleading, or at best controversial. Moreover, to the extent that Plaintiff asserts that state law required Mead Johnson to provide additional or different warnings and/or instructions, or

additional and/or different product labeling, such construction of state law would violate the First Amendment, including its prohibition against compelled speech.

PRAYER FOR RELIEF

WHEREFORE, Mead Johnson prays for judgment as follows on Plaintiff Collins's Complaint and Mead Johnson's Answer:

- A. Plaintiff Collins's Complaint be dismissed with prejudice and that Plaintiff Collins take nothing;
- B. That judgement be entered in favor of Mead Johnson and against Plaintiff Collins;
- C. Awarding Mead Johnson all reasonable expenses, including court costs and attorneys' fees, incurred by it in connection with this action; and
- D. Awarding Mead Johnson such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Mead Johnson hereby requests a jury on all issues triable by jury.

Dated: July 22, 2024

Respectfully submitted,

By: /s/ Maureen Bryan

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CERTIFICATE OF SERVICE

The undersigned certifies that on the **22nd** day of **July, 2024**, a true and correct copy of the foregoing was served via electronic mail, in Adobe PDF format, upon the following:

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